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10/057,321	09/24/2001	Roy A. Black	016761/0170	8287
22428	7590	07/01/2004	EXAMINER	
FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/057,321

Applicant(s)

BLACK ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 63-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63-76 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/4/02.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Application Status***

1. By virtue of a preliminary amendment filed on September 24, 2001, Claims 1-62 have been cancelled and Claims 63-76 have been added. Thus, Claims 63-76 are pending and will be examined herein.

### ***Priority***

2. The instant application is granted the benefit of priority for the U.S. non-Provisional Application Nos. 09/611,722 and 09/244,984 filed on July 6, 2000 and February 4, 1999, respectively, as requested in the declaration and the first lines of the specification. The instant application is also granted the benefit of priority for the U.S. Provisional Application Nos. 60/117,476, 60/135,499, and 60/073,709 filed on January 27, 1999, March 30, 1998, and February 4, 1999, respectively, as requested in the declaration and the first lines of the specification.

### ***Information Disclosure Statement***

3. The information disclosure statement filed on February 4, 2002 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

### ***Compliance with the Sequence Rules***

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, despite the filing of a sequence listing in computer readable form and paper copy on

June 18, 2002, this application fails to **fully** comply with the requirements of 37 C.F.R. § 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

a) On page 15, line 12, a peptide sequence is disclosed without SEQ ID NO identification. If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

#### ***Objections to the Specification***

5. The amendment filed September 24, 2001 is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment to the first paragraph incorporates all prior applications by references; however, only provisionals 60/135,499 and 60/073,709 are originally incorporated by reference. Although the amendment was filed on the filing date of the instant application, said amendment is not referred to in the declaration and is, thus, considered an amendment and not an original part of the specification (see M.P.E.P. §

608.04(b)). Applicant is required to cancel the new matter in the reply to this Office Action or to cite clear support (page and line number) for the amendment.

6. The specification is objected to for being unclear in its reference to specific residues in both the TACE sequence and the TNF- $\alpha$  sequence without correlating such reference to a full-length SEQ ID NO. The Examiner notes the following locations in the specification that require clarification:

- a) On page 3, first paragraph, "1-477", "Ser266", and "Asn542" are noted without description of a full-length SEQ ID NO.
- b) On pages 8-9, these references are again found along with references to Leu348 and Gly349.
- c) In the description of Figures 1 and 4, specific residues are cited without correlation to a full-length sequence.
- d) On page 12, references in the second and fourth paragraphs.
- e) On page 13, second full paragraph.
- f) On page 14 (top).
- g) On page 17, third paragraph.
- h) On pages 24-28 throughout.
- i) On page 31, first paragraph (continued from previous page).
- j) On page 34, first full paragraph.
- k) On page 36, second full paragraph.
- l) On page 39, lines 2-3.

7. The specification is objected to for being unclear on page 3, line 13, wherein "Asn542" is mentioned; however, the relative sequence is disclosed as having only 477 residues. Thus, the nature of residue 542 is wholly unclear. See also page 8, line 10. On page 13, line 15 (also on page 17, line 14 and page 34, line 8), the Examiner notes a residue "Asn452" is disclosed; perhaps "Asn542" is a typographical error? Clarification is required.

Also, on page 24, a Cys478 is described, which is also not within the range of 1-477 described earlier. Clarification is required.

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8. The specification is objected to for containing references to color figures (Figures 2a-2b) without their inclusion. Applicant must amend the description of the drawings or submit color drawings and amend the specification as required. Rules for submitting color figures are found in 37 C.F.R. § 1.84.

9. The specification is objected to for being confusing with respect to a reference. On page 22, line 14, WO 95/07619 is described as exemplifying hardware and software systems for protein modeling; however, this WO document is drawn to "Healthy Spread Fats" and does not describe molecular modeling whatsoever. Clarification is required.

### ***Claim Objections***

10. Claim 68 is objected to for omitting a conjunction between the two items (i) and (ii).

Insertion of an "and" is required.

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 67 and 74-76 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The additional limitations in Claims 67 and 74 are confusing as to the physical limitations they impose on the claimed computerized system. The specification provides no embodiments of said limitations so that the Examiner might be able to understand their intent. In fact, no description of the computer system used to model the

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disclosed crystal structure coordinates of Table 1 is exemplified. In Maskos *et al.* (see IDS), which is Applicant's journal publication of the disclosed coordinates, an SGI workstation was used with particular programs. It is unclear if SGI stations contain the limitations or if particular programs are required or none-of-the-above. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 63-65 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The concept of a computer readable medium comprising two program codes, one for data storage and one for data processing, is considered new matter. Original claims 22-25 are drawn to a computer readable medium with the crystal structure coordinates encoded thereon; no conception of program codes is supported here. Also, on page 31 of the specification as originally filed, computer readable media are described without reference whatsoever to program codes. Applicant is required to cite clear support (page and line number) in the originally filed disclosure for the alleged new matter or to cancel said new matter.

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13. Claims 66-76 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Partial support for Claim 66 can be found in original Claim 26; however, several limitations in the originally filed claim have been removed rendering Claim 66 broader than originally described. Partial support is also on pages 32-33, wherein again the description is of a species and Claim 66 is a genus of said species. Thus, the breadth of Claim 66 is not described in the specification as originally filed. The Examiner suggests combining all of Claims 66-69 so that Claim 66 encompasses the scope claimed in original Claim 26.

Also in Claims 66-76, the concept of “multi-dimensional”, as opposed to three-dimensional as originally filed, is considered new matter.

Applicant is required to cite clear support (page and line number) in the originally filed disclosure for the alleged new matter or to cancel said new matter.

14. Claims 63, 65, and 66-76 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to computer readable media having program code recorded thereon wherein said code stores any crystallographic structural data of any TACE polypeptide. The instant claims are also drawn to computerized system containing memory storing said structural data.



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To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The specification teaches the soluble TACE polypeptide from human; the specification also teaches its truncation, mutation, and His-tagging for purification and crystallographic studies of the resultant polypeptide (see page 3, first paragraph). The specification also teaches a particular crystal of said TACE polypeptide and its specific atomic coordinates in Table 1. Does this species adequately describe the claimed genus of any crystallographic structural data of any TACE polypeptide? A single species is disclosed. This single species cannot support description of the entire genus because no correlation between the disclosed species and all TACE polypeptides is described. Moreover, the single species is not of a full-length TACE polypeptide, the structure of which is left wholly undescribed. Therefore, Claims 63 and 65-76, as written, fail to satisfy the written description requirement.

### ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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15. Claims 66-69 and 74-76 are rejected under 35 U.S.C. § 102(a) as being anticipated by Cirilli *et al.* (see IDS). The instant claims are drawn to a computer, comprising memory, a processor, and a display, wherein said computer stores structural data of a TACE polypeptide in its memory, accesses and processes said data to produce output according to instructions, and displays said output in multidimensions on a computer screen using visual images. Claim 74 also indicates using a composition in addition to the TACE polypeptide.

Cirilli *et al.* teach modeling the TACE active site from a known adamalysin II active site (see page 321, right column); said modeling inherently comprises using both adamalysin II and TACE structural coordinates simultaneously. Said modeling is performed on a Silicon Graphics system (see page 320, left column), which is well known in the art to comprise all of the above limitations.

***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 70-73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cirilli *et al.* (see IDS). The instant claims are drawn to a computer, comprising memory, a processor, and a display, wherein said computer stores structural data of a TACE polypeptide in its memory, accesses and processes said data to produce output according to instructions, and displays said

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output in multidimensions on a computer screen using visual images, wherein said visual images are of ribbon structures, solid models, electrostatic surface potential, or stereo images.

Cirilli *et al.* teach as described above. Cirilli *et al.* also teach stereo images (see Fig. 1), surface potentials (see Fig. 3), and solid models (see Fig. 4) of the taught adamalysin II, although not specifically of the modeled TACE polypeptide. Ribbon structures, although not expressly taught by Cirilli *et al.*, as well known in the art as means for depicting protein structure data.

At the time of the invention, it would have been obvious to produce the modeled TACE polypeptide in any of the above visual images since Cirilli *et al.*, or the art, expressly teach the usefulness of such views in analyzing protein structure data. One would have been motivated to model the TACE polypeptide using such visual images to facilitate inhibitor studies noted as useful in the introduction of Cirilli *et al.*

### ***Response to Arguments***

17. The instant application is a continuation of 09/611,722. Applicant has amended the pending claims of the instant application to exactly recite those claims under final rejection in the parent application. Prior to abandonment, the single remaining ground of rejection in the parent application was a rejection under 35 U.S.C. § 103(a) rendering the pending claims unpatentable over Black *et al.* (USPN 5,830,742) in view of Gilliland *et al.* (see IDS), further in view of Hatada *et al.* (IDS document WO 97/08300), further in view of both Delisi *et al.* (USPN 5,583,973) and Smith (see IDS). The Examiner notes that USPN 5,830,742 and 09/611,722 shared a common inventor.

In Applicant's remarks in the instant application, in conjunction with the preliminary amendment filed so that identical claims are pending to the parent application, Applicant argues

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that USPN 5,830,742 and the instant application were commonly owned at the time of the invention. This argument is persuasive because

“For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See M.P.E.P. § 706.02(l)(1) and § 706.02(l)(2).”

and Applicant has stated as much in their remarks.

### *Conclusion*

18. Claims 63-76 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Examiner  
Art Unit 1652

June 22, 2004